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Comments from the
National Family Planning and Reproductive Health Association (NFPRHA)

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"Maximize the Potential of Emergency Contraception to Reduce Unintended Pregnancy and Abortion: Switch Plan B® From Rx to OTC "

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My name is Gretchen Sauer Stuart, M.D., MPHTM and I appreciate the opportunity to submit comments in support of the application to make Plan B® Emergency Contraceptive pills available over the counter (OTC). I am a practicing obstetrician/gynecologist in Dallas, Texas. I am also an Assistant Professor at the University of Texas Southwestern Medical Center where I care for many women of reproductive age, including teenagers, who receive a range of services at our community women's health centers. I am testifying today on behalf of the National Family Planning and Reproductive Health Association (NFPRHA).

A national non-profit membership organization based in Washington, DC, NFPRHA represents clinics that provide reproductive health care to nearly five million low-income women each year at more than 4600 public health clinics nationwide that are supported with federal funds such as Title X of the Public Health Services Act. NFPRHA members include private non-profit clinics; state, county and local health departments; Planned Parenthood Federation of America affiliates; family planning councils and hospital-based clinics. Title X funded clinics are often the entry point into the health care system for women and families who otherwise lack access to health care services. The vast majority of Title X clients are uninsured and do not qualify for Medicaid, and almost one-third of clients are under age 20.[1]

The task before you is to determine whether Plan B meets the U.S. Food and Drug Administration's (FDA) criteria for over-the-counter drugs. You have heard from exemplary witnesses who have expertly made the case that Plan B is indeed safe, effective and easy to use. NFPRHA, along with the medical community, including the American College of Obstetricians and Gynecologists (ACOG), the American Medical Association (AMA), and women's health advocates, overwhelmingly endorses the switch from prescription to over-the-counter status for Plan B. I will use my time to make the case that not only does Plan B meet FDA's criteria for making the switch to OTC status, but that it is good public health policy to do so.

I want to offer a brief reminder about the health benefits of contraception—something we all intuitively know but bears repeating because public opinion on this issue actually plays an important role in women having access to contraception. In 1999, the Centers for Disease Control and Prevention (CDC) included family planning in their published list of the "Ten Great Public Health Achievements in the 20th Century." Further recognizing that avoiding unintended pregnancy improves maternal and child health, one of the CDC's Healthy People 2010 objectives is for 70% of all pregnancies to be intended. Let's be clear, pregnancy is not without risk so this would seem to be an appropriate point of comparison.

No matter how squeamish the American public and policymakers may feel about sex, the reality is that contraception is basic health care for women throughout much of their lives. An average woman who wants two children will spend five years pregnant or trying to get pregnant and roughly 30 years trying to prevent pregnancy.[2] For most women, access to contraception is essential to avoiding unintended pregnancy. Contraception also improves the health of women and children by enabling women to

plan and space their births. Also, the ability to plan whether and when to have children improves the economic security of all couples—this is especially true of sexually active teenagers. Less than one-third of teen mothers ever finish high school, leaving many unprepared for the job market and more likely to raise their children in poverty.[3]

Sadly, the United States has one of the highest rates of unintended pregnancy among Western nations. Each year, almost half of the 6.3 million pregnancies in this country are unintended, and almost half of those end in abortion.[4] Despite impressive declines over the past decades, the U.S. also has the highest rates of teen pregnancy in the industrialized world and 80 percent of teen pregnancies are unintended.[5] Nearly half of all unintended pregnancies occur among the 7% of women who did not use any method of contraception.[6] However, over half (53%) of unintended pregnancies occur among those women who experience a contraceptive failure.[7] In addition, women do not always have control over the timing of sexual intercourse or the use of contraception. Unfortunately, rape, coercion and other pressures also interfere with the use of contraception.

While there are many reasons that unintended pregnancies occur, a major reason is lack of access to contraception. This is a significant problem among women without regular health insurance, especially young women-- the very women who comprise the majority of clients served in Title X-funded family planning clinics and in the clinics where I practice.

In a nutshell, making Plan B available over the counter would greatly expand access to this safe and highly effective method to reduce unintended pregnancy, and in turn, recourse to abortion. Emergency contraception (EC) has the potential to cut the staggering rates of unintended pregnancy and abortion in half, but most women have very limited knowledge of or access to it.[8] Time is of the essence in maximizing the enormous potential of EC. The sooner a woman takes EC after unprotected sex, the more effectively it works to avoid unintended pregnancy. Taken within 72 hours after unprotected sex or birth control failure, Plan B reduces the average risk of pregnancy among users by 89%.[9] It is also imperative to remove the prescription requirement so that women can access Plan B when it is most effective.

And because I practice in publicly funded clinics that are chronically struggling to meet the growing demand for services with ever shrinking public resources, I feel it is important to note that reducing unintended pregnancy saves scarce public health dollars. Studies indicate that EC could save up to $500 per year for each woman covered by public and managed-care health services.[10]

Supporters of making Plan B available OTC are not seeking to increase the need for this product. As the label says, it is not a substitute for regular contraception. We are simply promoting efforts to make it more readily available to women who wish to avoid an unintended pregnancy. An analysis conducted in 2002 by The Alan Guttmacher Institute estimated that increased use of EC accounted for up to 43% of the total decline in the abortion rate between 1994 and 2000.[11]

In my practice I write EC prescriptions for women of all ages who are seeking reproductive health care so they can manage their futures. Unfortunately, EC can be difficult to obtain within the short window of effectiveness: in most states a woman must call or visit a health care provider to get a prescription, she must then find a pharmacy that stocks it, and collect the funds to pay for it. There are hurdles at every step in this process.

Often the need for EC will arise on weekends. Even my regular patients will experience some delay in obtaining a prescription over the weekend and then, in finding a pharmacy that stocks it. However, for the uninsured women who use our public health clinics, the barriers in obtaining EC within the limited time frame for effectiveness are often insurmountable. Many of these women are inexperienced with the medical system and may be intimidated to make a cold call to a health care provider. In addition, our public health clinics, like private doctors offices, are closed or have limited hours on the weekends. For many low-income women, transportation is also a significant barrier. All of these barriers are exacerbated for teens. And, most tragically, a victim of rape may not have the emotional or physical energy needed to go through the hoops women must currently go through in getting emergency contraception.

Making Plan B available over the counter would dramatically reduce the significant barriers to access for this proven preventive method of contraception. Although five states (Alaska, California, Hawaii, New Mexico, Washington) have established collaborative practice agreements to enable women to obtain EC directly from pharmacists without a prescription, even this welcome effort to increase access falls far short of the expanded access that OTC status would provide. A recent study published in the November 2003 issue of *Obstetrics and Gynecology,* ACOG's professional journal, found that of 89 pharmacies in Albuquerque, NM, only 11% of the pharmacies visited had EC products in stock. Although 53% reported they could obtain the product within 24 hours, this is of limited value for women needing a product that is most effective the earlier it is used.[12]

I also want to briefly allay any doubts about the potential for negative health consequences that might result from easier access to EC. As a physician who specializes in reproductive health I am often asked whether I think that easier access to EC would undermine consistent use of regular contraceptives. Studies indicate that this is not the case and that women with advance provision of EC are no more likely to engage in unprotected sex and no more likely to use their regular contraceptive methods less effectively.[13] [14] [15] Studies have also found that frequent repeated use of EC is uncommon, even among adolescents.[16] [17] [18] [19] I am also careful to inform my patients that EC is less effective than regular forms of contraception and does not protect against infection with STDs.

In addition, because I serve a lot of teen patients, I am often asked whether EC is safe for teens and whether teens would be more likely to engage in unprotected sex if they know they can use EC. I mention this because I am worried that these unfounded concerns

could be the basis for arguments to impose some sort of restrictions on teen access to Plan B should it be made available over-the-counter. I am aware of how politically sensitive the topic of teenage sex is for most people. However, given the extremely high rates of sexual activity among teens and the continuing high rates of unintended pregnancy, I strongly urge you to recognize the reality that health care providers face by not recommending any restrictions on teen access should Plan B be available over-the-counter. In my experience, these are the women who have the most to lose when faced with an unintended pregnancy, and the most to gain from avoiding it.

Specifically, in terms of safety, Plan B poses no special safety concerns for teens or adults. I won't belabor the safety issue because many of the expert witnesses appearing today have provided ample evidence supporting the safety of Plan B, but as a physician I will emphasize that safety regarding this product is not an issue even for teens. In fact, the health risks associated with unintended pregnancy are much greater than those posed by use of Plan B.

In addition, I can say unequivocally that easier access to EC will not cause non-sexually active teens to start having sex or sexually active teens to start having unprotected sex. There is no basis for such arguments in my professional experience and from a policy perspective it is clear that levels of sexual activity show no correlation to the availability of contraception. In fact, studies have shown that in countries with greater access to EC that teens are no more likely to engage in unprotected sex.[20]

In considering issues regarding teenagers and emergency contraception it is important to remember the obvious-- regardless of what we think about teen sexual activity, teens who are seeking emergency contraception have *already* been sexually active and want to act responsibly to avoid unintended pregnancy. Because the consequences of unintended teen pregnancy are so great -- medically, socially, and economically-- restricting access to Plan B for teens would amount to bad public policy.

Plan B emergency contraception is a safe and effective back up form of contraception that should not be seen as more controversial than other methods. It is unique in its enormous potential to dramatically advance the important public health goals of reducing unintended pregnancy and abortion. Opinions vary widely on why the U.S. rates of unintended pregnancy are so shamefully high, but there is unanimous agreement that it is indeed too high. If we have a product available that can move us toward our shared public goal of ensuring that all pregnancies are wanted pregnancies, then there seems to be no good reason to delay making it widely available. Making Plan B available over the counter would represent a tremendous advancement for women's health and the public health in general. There is certainly no medical reason for not making Plan B available without a prescription and from a public health perspective there is every reason to do so.

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